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PTO/SB/21 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	6320,030 Pat. No.
Filing Date	10/26/2000
First Named Inventor	Ashok K SHUKLA
Group Art Unit	
Examiner Name	KOUSTANTINA KATHEVES
Total Number of Pages in This Submission	
Attorney Docket Number	

ENCLOSURES *(check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment / Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Assignment Papers *(for an Application)*
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below)*: CERTIFICATE OF CORRECTION MAY 0 6 2002

Remarks: Certificate of Correction

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Ashok K SHUKLA
Signature	
Date	4/19/02

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: _____

Typed or printed name	Ashok K SHUKLA		
Signature		Date	4/19/02

Paper No. _____

U.S. DEPARTMENT OF COMMERCE
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PATENT NO.	PATENT DATE
6320,030	Nov. 20, 2001
PATENTEE	
Ashok K. Shukla et al	

MAILING DATE

CERTIFICATE
DEC 11 2001
OF CORRECTION

NOTIFICATION OF RETURN OF PAPERS
RE REQUEST FOR CERTIFICATE OF CORRECTION

The request for a Certificate of Correction in the above-identified patent is returned herewith, together with the PTO 1050 forms, for the reason(s) checked below.

☒ 1. Needs transmittal letter. The request is unsigned. The request must be properly signed before it will be considered.

☐ 2. The request does not specifically designate the column and line numbers wherein the errors appear in the patent. A substitute request providing this information is required for proper consideration.

☐ 3. The Form PTO-1050 submitted with your request is not suitable for printing purposes. See the instructions on the blank Form PTO-1050 enclosed.

☐ 4. The Patent No., as shown on the papers, appears to be incorrect because:

- ☐ a. The Patent No. on the request and on the PTO-1050 do not agree.
- ☐ b. The name of the patentee on the patented file does not agree with that shown on the the enclosed papers.

☐ 5. The record reveals that there is no power of attorney to you in this case. A written power or authorization from the patentee, or assignee if any, must be submitted before the request may be considered.

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- ☐ a. Amendment purported to be under Rule 312.
- ☐ b. Assignment.
- ☐ c. Priority papers.
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☐ 7. Other:

☐ A. PLEASE RETURN A COPY OF THIS LETTER TOGETHER WITH THE ENCLOSED PAPERS AS CORRECTED TO ENSURE EXPEDIENT ASSOCIATION WITH THE FILE.

☐ B. Enclosed are copies of PTO-1050 for use in typing the subject matter to be printed on the Certificate. This will avoid delay in handling the request. (See 862 O.G.2.).

Head, Decision and Certificate
of Correction Branch

FORM PTOL-396 (8/75)

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Patent no : 6,320,030

PTO/SB/44 (02-01)
Approved for use through 01/31/2004. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.
(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO : 6,320,030 B1
DATED : NOV. 20. 2001
INVENTOR(S) : ASHOK K SHUKLA, MUKTA M. SHUKLA & AMITA M. SHUKLA

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In claim 14, 15, 16, 17 and 19.

"The mucin-DNA Complex of claim 2"

Should be replaced by

--The mucin-biomolecule complex of claim 2--

NOTE! In claim 2, There is no phrase "mucin-DNA". It was typo by examiner and it is overlooked by inventors, when letter sent by examiner. Please make This change or Correction in above patent.

Thanking you in advance

Sincerely

(ASHOK K. SHUKLA)

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PATENT NO. _____

No. of additional copies ⇨

US006320030B1

(12) **United States Patent**
Shukla et al.

(10) **Patent No.: US 6,320,030 B1**
(45) **Date of Patent: Nov. 20, 2001**

(54) **MUCIN-BIOMOLECULES COMPLEX FOR TRANSFECTION**

(76) Inventors: **Ashok K Shukla; Mukta M Shukla; Amita M Shukla**, all of 10423 Popkins Ct., Woodstock, MD (US) 21163

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/696,897**

(22) Filed: **Oct. 26, 2000**

(51) **Int. Cl.**[7] **C12N 15/00**; C12N 15/09; C12N 15/63; C12N 15/70; C02G 79/00

(52) **U.S. Cl.** **530/395**; 435/6; 435/7.1; 435/320.1

(58) **Field of Search** 435/6, 7.1, 320.1; 530/395

(56) **References Cited**

PUBLICATIONS

Martin Thurnher et al. Carbohydrate receptor–mediated gene tmasfer to human T leukaemic cells Glycobiology vol. No. 4 pp. 429–435, 1994.*

* cited by examiner

Primary Examiner—Andrew Wang
Assistant Examiner—Konstantina Katcheves

(57) **ABSTRACT**

In the present invention we describe a new method for the formation of a mucin-biomolecules complex, such as a mucin-DNA (deoxyribonucleic acid) complex and the application of such a complex for the transport of DNA, RNA (ribonucleic acid) and other biomolecules into cells. Transfection is the introduction of a DNA molecule into a eukaryotic cell, usually followed by the expression of one or more genes in the newly introduced DNA. The mucin-DNA complex described in the present invention can be used to perform transfection of DNA, as well as, the introduction of RNA and other larger biomolecules into cells. Since effective transfection, especially in in vivo systems is still limited by the methods currently available, the mucin-DNA complex, as described in the present invention, presents a novel and significantly improved method for performing transfection and ensuring the effective transmission of DNA into cells and the expression of genes in transfected DNA.

17 Claims, 5 Drawing Sheets

minutes. The mucin was precipitated by the addition of isopropanol or other organic solvents. The resulting precipitate showed fluorescence whereas the remaining solution showed no fluorescence.

EXAMPLE 2

Stress Induction on a Newly Formed Mucin-DNA Complex

Fluorescence tagged DNA was added to a mucin solution and the mixture was agitated by the use of a vortex for 1–2 minutes. The mucin was precipitated by the addition of a gallnut extract, a natural product which has mucin precipitating properties. After precipitation the mucin-DNA complex showed fluorescence while the remaining solution showed no fluorescence, indicating that all of the DNA had combined with the mucin to form a mucin-DNA complex. The mucin-DNA complex was re-suspended in water and centrifuged for 1–2 minutes. Again, only the mucin-DNA complex showed fluorescence while the supernatant showed no fluorescence. Thus, the mucin-DNA complex formed, according to the present invention, is highly stable.

While a specific embodiment of the invention has been shown and described in detail to illustrate the application of the principles of the invention, it is understood that the invention may be embodied otherwise without departing from such principles and that various modifications, alternate constructions, and equivalents will occur to those skilled in the area given the benefit of this disclosure and the embodiment described herein, as defined by the appended claims.

What is claimed is:

1. A mucin-DNA (deoxyribonucleic acid) complex formed by combining mucin and DNA wherein the complex is capable of transport into a cell.

2. A mucin-biomolecules complex formed by combining mucin and biomolecules wherein the complex is capable of transport into a cell.

3. The mucin-DNA complex of claim 1, where said mucin is selected from the group consisting of mucin from a biological source, mucin from a non-biological source and combinations thereof.

4. The mucin-DNA complex of claim 1, where said mucin is selected from the group consisting of mucin in its native state, biologically modified mucin, chemically modified mucin, mucin modified by enzymes, mucin modified by heat-based methods and combinations thereof.

5. The mucin-DNA complex of claim 1, where said mucin contains sialic acid.

6. The mucin-DNA complex of claim 1, where said DNA is selected from the group consisting of DNA in its natural state, modified DNA, synthetically created DNA, linear DNA, circular DNA, single-stranded DNA, double-stranded DNA and combinations thereof.

7. The mucin-DNA complex of claim 1, where said complex is purified by a method selected from the group consisting of chromatographic methods, centrifugation methods and, combinations thereof.

8. The mucin-DNA complex of claim 1, where said mucin in said complex is modified by the addition, removal or alteration of a carbohydrate or a protein component of said mucin.

9. A mucin-DNA complex as in claim 1, where said mucin in said complex is modified to target specific cells as the targets of transfection.

10. A mucin-biomolecules complex as in claim 2, where said biomolecules are selected from the group consisting of DNA, RNA, nucleic acids, proteins, peptides, antibodies, glycolipids, glycoproteins, natural polymers, synthetic polymers, modified polymers, and combinations thereof.

11. The mucin-biomolecules complex of claim 2, where said biomolecules is selected from the group consisting of biomolecules in its natural state, modified biomolecules, synthetically created biomolecules and combinations thereof.

12. The mucin-DNA complex of claim 2, where said mucin is selected from the group consisting of mucin from a biological source; mucin from a non-biological source; and, combinations thereof.

13. The mucin-DNA complex of claim 2, where said mucin is selected from the group consisting of mucin in its native state; biologically modified mucin; chemically modified mucin; mucin modified by enzymes; mucin modified by heat-based methods; and, combinations thereof.

14. The mucin-DNA complex of claim 2, where said mucin contains sialic acid.

15. The mucin-DNA complex of claim 2, where said complex is purified by a method selected from the group consisting of chromatographic methods, centrifugation methods, and, combinations thereof.

16. The mucin-biomolecules complex of claim 2, where said complex the addition, removal or alteration of a carbohydrate or a protein component of said mucin.

17. The mucin-DNA complex of claim 2, where said mucin in said complex is modified to target specific cells as the targets of transfection.

* * * * *

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Assistant Commissioner for Patents

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